

K111937

FEB - 8 2012

5. 510(k) Summary

ClearFlash, Incorporated – ClearFlash AC2100 Cosmetic System

This 510(k) Summary is submitted in accordance with 21 CFR Part 807, Section 807.92(c).

| | |
|---|---|
| Owner Name and Address | ClearFlash Technologies, Inc. 901 South Mopac Expressway Barton Oaks Plaza One, Suite 300 Austin, TX 78746 (949) 949-295-6594 (Phone) (949) 334-0089 (Fax) |
| Contact Info | Joseph Neev 2706 S. La Paz Rd. #108 Aliso Viejo, CA 92656-3041 (949) 295-6594 (Phone) (949) 334-0089 (Fax) |
| Date Prepared | June 30 th , 2011 |
| Device Trade Name | ClearFlash AC2100 Cosmetic System |
| Common Name | Acne Treatment Device |
| Classification Name | Class II – Laser instrument, surgical, powered (21 CFR 878.4810, Product Code OLP) |
| Predicate Devices and 510(k) Numbers | ThermaClear Device (K060653) Zeno Acne Device (K043377) Radiancy ClearTouch Lite (K060411) |

| | |
|--------------------------------|---|
| Description of Device | <p>The ClearFlash AC2100 is a compact, handheld device that delivers a controlled pulse of thermal energy to the skin for treating dermatological disorders, specifically, mild to moderate inflammatory acne. An acne lesion is treated by applying the tip of the ClearFlash AC2100 device to the skin area and pressing a pulse activation button that releases a controlled amount of thermal energy into the skin. After the pulse is delivered to the skin the ClearFlash AC2100 device is removed from the acne lesion and the treatment is complete. The treated area on the skin can then be cleaned with an over-the-counter astringent. The ClearFlash AC2100 device is powered by a 9V battery.</p> |
| Indications for Use | <p>The ClearFlash AC2100 Cosmetic System is indicated for the treatment of individual acne pimples in persons with mild to moderate inflammatory acne.</p> |
| Performance Data | <p>Laboratory bench top testing demonstrated that the ClearFlash AC2100 device performed similarly to the predicate devices.</p> |
| Substantial Equivalence | <p>The ClearFlash AC2100 and predicate devices deliver thermal energy into the skin through different methods to treat mild to moderate inflammatory. Minor differences in the technological characteristics of the ClearFlash AC2100 device compared to predicate devices does not raise any new safety or efficacy issues. Therefore, the ClearFlash AC2100 device is substantially equivalent to the predicate devices.</p> |
| Conclusion | <p>Based on the indications for use, technological characteristics, performance testing and comparisons to predicate devices, the ClearFlash AC2100 has been shown to be safe and effective for its intended use.</p> |



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

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ClearFlash Technologies, Inc.
% Mr. Joseph Neev
Regulatory Consultant to CFT, Inc.
2706 S. La Paz Road, #108
Aliso Viejo, California 92656-3041

Re: K111937

Trade/Device Name: ClearFlash AC2100 Cosmetic System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and
plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: OLP
Dated: January 19, 2012
Received: January 23, 2012

Dear Mr. Neev:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

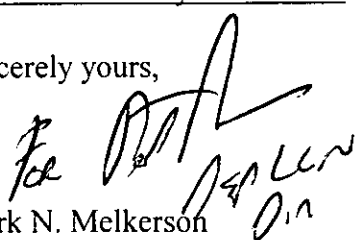
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use Statement

510(k) Number (if known): K111937

Device Name: ClearFlash AC2100 Cosmetic System

Indications for Use:

The ClearFlash AC2100 Cosmetic System is indicated for the treatment of individual acne pimples in persons with mild to moderate inflammatory acne.

Prescription Use _____

AND/OR

Over-The Counter Use X

(Part 21 CFR 801 Subpart D)

(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogle for *mxm*
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111937